ARC 3985C

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to interchangeable biological products and labeling requirements

The Board of Pharmacy hereby amends Chapter 18, "Centralized Prescription Filling and Processing," and Chapter 22, "Unit Dose, Alternative Packaging, and Emergency Boxes," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 147.76 and 155A.28.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 155A.28 and 155A.32 and 2017 Iowa Acts, House File 305.

Purpose and Summary

The amendments incorporate language from 2017 Iowa Acts, House File 305, signed into law during the 2017 Legislative Session of the 87th General Assembly, which allows the substitution of interchangeable biological products and includes labeling requirements.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on April 25, 2018, as **ARC 3764C**. The Board received one comment from the Iowa Pharmacy Association in support of the amendments. No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Board on July 24, 2018.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on October 3, 2018.

The following rule-making actions are adopted:

ITEM 1. Amend subrule 18.3(4) as follows:

18.3(4) *Central fill label requirements.* The label affixed to the prescription container filled by a central fill pharmacy on behalf of an originating pharmacy shall include the following:

a. to *c.* No change.

d. ~~The~~ Except as provided in 657—subrule 8.19(7) for epinephrine auto-injectors or 657—subrule 8.19(8) for opioid antagonists, the name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner;

e. to *g.* No change.

h. Unless otherwise directed by the prescriber, the name, strength, and quantity of the drug dispensed.

(1) If a pharmacist selects an equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label shall identify the generic drug and may identify the brand name drug for which the selection is made, such as "(generic name) Generic for (brand name product)"~~.~~;

(2) If a pharmacist selects a brand name drug product for a generic drug product prescribed by a practitioner, the prescription container label shall identify the brand name drug product dispensed and may identify the generic drug product ordered by the prescriber, such as "(brand name product) for (generic name)";

(3) If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the prescription container label shall identify the interchangeable biological product dispensed and may identify the biological product prescribed by the practitioner, such as "(interchangeable biological product) for (biological product)";

i. The initials or other unique identification of the pharmacist who performed drug use review.

ITEM 2. Amend subrule 22.1(3) as follows:

22.1(3) *Labeling requirements.*

a. and *b.* No change.

c. If a pharmacist selects a generically equivalent drug product for a brand name drug product prescribed by a practitioner, the label must identify the generic drug and may identify the brand name drug for which the selection is made. The dual identification allowed under this paragraph must take the form of the following statement on the label: "(generic name) Generic for (brand name product)". If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the label shall identify the interchangeable biological product dispensed and may identify the biological product prescribed by the practitioner, such as "(interchangeable biological product) for (biological product)".

d. and *e.* No change.

ITEM 3. Amend subrule 22.5(5) as follows:

22.5(5) *Labeling requirements.*

a. to *c.* No change.

d. If a pharmacist selects a generically equivalent drug product for a ~~brand-name~~ brand name drug product prescribed by a practitioner, the label must identify the generic drug and may identify the ~~brand-name~~ brand name drug for which the selection is made. The dual identification allowed under this paragraph must take the form of the following statement on the label: "(generic name) Generic for (~~brand-name~~ brand name product)". If a pharmacist selects an interchangeable biological product for the biological product prescribed by a practitioner, the label shall identify the interchangeable

biological product dispensed and may identify the biological product prescribed by the practitioner, such as "(interchangeable biological product) for (biological product)".

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 8/29/18.